

IN THE CLAIMS

Please amend the claims as indicated in the following set of claims, which includes new claims 64-72; also, claim 60 is cancelled.

1.-16. (Canceled)

17. (Currently Amended) A method of treating the wall of a blood vessel from within the lumen thereof, with a radiation catheter including a radiotherapy lumen, a longitudinally channeled distal balloon, and a balloon inflation lumen, the method comprising the steps of:

inserting said catheter into the vessel lumen until said balloon is adjacent a target site of the vessel wall to be treated;

inflating said balloon to substantially center said catheter radiotherapy lumen within the vessel lumen at the target site while allowing perfusion of blood past the inflated balloon through channels formed thereby;

advancing a radioactive source into said catheter radiotherapy lumen to position said source within a region thereof along a portion of the catheter occupied by said balloon; and

withdrawing said source after being positioned within said region for a predetermined interval of time.

18. (Currently Amended) The method of claim 17, wherein the step of inserting of the catheter into the vessel lumen is performed by steering said catheter over a guide wire previously inserted into the vessel lumen past the target site.

19. (Currently Amended) The method of claim 17, wherein the ~~step of advancing of~~ radioactive source into the catheter radiotherapy lumen is performed by advancing a source wire having said radioactive source secured at its distal end.

20. (Currently Amended) The method of claim 19, ~~including the step of using~~ wherein the source wire is a super-elastic source wire ~~with said distal radioactive source.~~

21. (Previously Presented) The method of claim 17, including selecting a radioactive source with a predetermined activity level, and setting said predetermined time interval in which the radioactive source is positioned within said region, to deliver a radiation dosage of from about 1,000 rads to about 1,500 rads to tissue in the vessel wall in proximity to the vessel lumen at the target site.

22. (Currently Amended) The method of claim 17, further ~~including the step of comprising~~ removing the catheter from the vessel lumen after the radioactive source has been withdrawn.

23. (Currently Amended) A method of treating a body duct with a centering catheter from within the lumen of the duct, which comprises:

inserting the centering catheter into the lumen of the body duct to position a centering device of said catheter at a site of the duct to be treated;

deploying said centering device of the catheter to position a radiotherapy lumen of the catheter at substantially the radial center of the lumen of the duct at said site, said centering device allowing perfusion while the centering device is deployed;

advancing material having a predetermined level of radioactivity into said radiotherapy lumen of the catheter to a position at said site; and
retracting said radioactive material after a predetermined time interval at said site.

24. (Previously Presented) The method of claim 23, wherein the centering device is a balloon secured distally about the catheter with lobes forming channels along the distally secured portion, to position said radiotherapy lumen at substantially the radial center of the lumen of the duct at said site when the balloon is inflated for said deployment.

25. (Previously Presented) The method of claim 23, including inserting the centering catheter into the lumen of the duct over a guide wire previously inserted therein.

26. (Previously Presented) The method of claim 23, including advancing said radioactive material into the radiotherapy lumen of the catheter on a super-elastic wire.

27. (Previously Presented) The method of claim 23, including designating said predetermined radioactivity level and said predetermined time interval to produce a radiation dosage of from about 1,000 rads to about 1,500 rads to tissue in the wall of the duct in proximity to the lumen of the duct at said site.

28. (Currently Amended) A method of inhibiting stenosis at a target site in a blood vessel, which comprises:

introducing radioactive material of predetermined radioactivity level at substantially the radial center of the lumen of the vessel at said site; leaving said radioactive material substantially centered in the vessel lumen, while perfusion is allowed through the vessel lumen, at said site for a predetermined period of time; and

immediately after said time period expires, removing the radioactive material from the site.

29. (Previously Presented) The method of claim 28, including introducing said radioactive material at substantially the radial center of the lumen of the vessel at said site through a radiotherapy lumen of a longitudinally fluted balloon catheter previously inserted into the vessel lumen and whose balloon has then been inflated for radially centering said radiotherapy lumen at said site and permitting blood flow past the inflated balloon.

30. (Previously Presented) The method of claim 29, including introducing the radioactive material through said radiotherapy lumen of the balloon catheter in a manner to maintain the radioactive material confined at substantially the radial center of the lumen of the vessel at said site.

31. (Previously Presented) The method of claim 30, wherein said radioactive material is confined within the distal end of a wire configured to enable rapid travel through the radiotherapy lumen of said balloon catheter to the target site.

32. (Previously Presented) The method of claim 30, wherein said predetermined radioactivity level and said predetermined time period are computed to achieve delivery of from about 1,000 rads to about 1,500 rads to tissue in the wall of the duct in proximity to the lumen of the duct at said site.

33. (Currently Amended) A method of inhibiting restenosis in a blood vessel at a narrowed region of the lumen thereof to be treated by an angioplasty procedure, which comprises ~~the steps of~~:

performing the angioplasty procedure;

substantially immediately thereafter introducing radioactive material of predetermined radioactivity level for a predetermined interval of treatment time, during which perfusion is allowed, at substantially the radial center of the lumen of the blood vessel along said narrowed region at which said angioplasty procedure was performed; and

removing said radioactive material from the blood vessel after said treatment time interval has elapsed.

34. (Previously Presented) The method of claim 33, including maintaining said radioactive material at substantially the radial center of the vessel lumen at said region for

the entirety of said treatment time interval without blocking the flow of blood through the vessel along said region.

35. (Previously Presented) The method of claim 34, including introducing and maintaining said radioactive material at substantially the radial center of the vessel lumen at said region thereof through a radiotherapy lumen of a balloon catheter inserted into the vessel lumen and with its balloon inflated at said region to form channels for both the radial centering and blood flow.

36. (Previously Presented) The method of claim 35, including conveying the radioactive material through said radiotherapy lumen of the balloon catheter by means of an elongate member.

37. (Previously Presented) The method of claim 33, including establishing said predetermined radioactivity level and said predetermined treatment time interval to result in the delivery of a prescribed dosage of radiation to tissue in the vessel wall in said region.

38. (Currently Amended) A therapeutic process for alleviating hyperplasia in a body duct, which comprises:

irradiating the wall of the duct, while allowing perfusion through the duct, with source material of predetermined radioactivity level positioned at substantially the radial center of the lumen of the duct at a preselected site; and

immediately after a predetermined period of irradiation has elapsed, removing the source material from said site.

39. (Previously Presented) The method of claim 38, including performing said irradiation with said source material contained within a therapy lumen of a balloon catheter inserted into the lumen of the duct and with its balloon shaped when inflated at said site to form radial centering channels for said therapy lumen.

40. (Previously Presented) A therapeutic process for alleviating hyperplasia in a fluid-carrying duct of a patient's body, which comprises:

irradiating the wall of the duct with source material of predetermined radioactivity level positioned at substantially the radial center of the lumen of the duct at a preselected site which has been subjected to trauma, while concurrently allowing passage of fluid through the duct past the position of the source material; and

immediately after a predetermined period of irradiation has elapsed, removing the source material from said site.

41. (Previously Presented) The method of claim 40, wherein irradiating the duct wall is performed by first inserting into the lumen of the duct a balloon catheter whose balloon is shaped to form inflation lobes along the catheter adapted to substantially radially center a lumen of the catheter when the balloon is inflated in the duct, positioning and then inflating said balloon at said site for said centering of the catheter lumen and to allow

passage of fluid through channels between said lobes past the inflated balloon at said site, and thereafter conveying said source material through said catheter lumen to said site.

42. (Previously Presented) The method of claim 41, including conveying said source material through said catheter lumen to said site on a super-elastic wire adapted to navigate curves in a path through the catheter lumen created by the duct.

43. (Previously Presented) The method of claim 42, further including deflating and withdrawing said balloon catheter from the lumen of the duct after said removal of the source material.

44. (Previously Presented) An angioplasty procedure which comprises:
opening a narrowed region in the lumen of a blood vessel of a patient to increase blood flow therethrough;
thereafter irradiating the wall of the vessel with a source of predetermined radioactivity level positioned at substantially the radial center of the opened lumen along the previously narrowed region, while concurrently allowing passage of blood through the vessel past the site of the radioactive source; and
after completing a predetermined period of irradiation, removing said source from the vessel.

45. (Currently Amended) The angioplasty procedure of claim 44, wherein the step of irradiating of the vessel wall is performed by first inserting into the lumen of the vessel a

centering catheter having a distal portion of its length sized and shaped to substantially radially center a lumen of the catheter in the vessel while allowing said passage of blood at the previously narrowed region, halting insertion of the centering catheter when said distal portion thereof is situated at the previously narrowed region, and then delivering said radioactive source through said catheter lumen to a desired location along said distal portion thereof.

46. (Previously Presented) The angioplasty procedure of claim 45, including delivering said radioactive source through said catheter lumen on a super-elastic wire.

47. (Previously Presented) The method of claim 45, further including withdrawing said centering catheter from the vessel lumen after removal of the radioactive source from the vessel.

48. (Previously Presented) A method of inhibiting stenosis at a target site in a coronary artery of a patient's body, which comprises:

inserting a radiation catheter with a distally secured longitudinally fluted centering balloon through a portion of the patient's cardiovascular system until said balloon is at said target site;

inflating said balloon to substantially align a radiotherapy lumen of said catheter with the longitudinal axis of the coronary artery at said target site while securing said catheter thereat and enabling blood flow past the inflated balloon through longitudinal flutes thereof;

advancing the distal tip of a dummy wire through the radiotherapy lumen of the catheter to said target site, from delivery apparatus coupled to the proximal end of said catheter, and retracting the dummy wire back into the delivery apparatus while retaining a measurement of the distance traveled by the distal tip of the dummy wire to reach said target site;

advancing a radioactive distal tip of a source wire of predetermined radioactivity level from said delivery apparatus through the radiotherapy lumen of the catheter the same distance traveled by the distal tip of the dummy wire for positioning at said target site;

retracting the source wire back into the delivery apparatus after a predetermined time interval has elapsed with the radioactive tip of the source wire positioned at the target site; and

deflating said balloon and removing the radiation catheter from the patient's body.

49. (Previously Presented) The method of claim 48, including using a super-elastic material for all but the radioactive portion of the source wire.

50. (Previously Presented) The method of claim 49, including selecting a nickel-titanium alloy as the super-elastic material.

51. (Currently Amended) The method of claim 48, ~~including performing the steps of advancing and retracting wherein the source wire through the radiotherapy lumen of the catheter from and is retracted~~ to a radiation-proof safe in said delivery apparatus.

52. (Previously Presented) The method of claim 48, including inserting said radiation catheter over a guide wire previously inserted into the cardiovascular system at least as far as the target site in the coronary artery, and

keying the coupling of the proximal end of the catheter to said delivery apparatus to restrain the catheter and guide wire from undergoing rotation in the cardiovascular system during performance of the method.

53. (Previously Presented) The method of claim 48, including predetermining values of said predetermined radioactivity level and said predetermined time interval to result in delivery of a dose of radiation in a range from about 1,000 rads to about 1,500 rads to tissue in the coronary artery wall in proximity to the radioactive tip at the target site prior to retracting the source wire therefrom.

54. (Previously Presented) A method of inhibiting stenosis at a target site in a blood vessel, which comprises:

introducing a radiation catheter, having a radiotherapy lumen with a proximal opening and a distal sealed end and having a channeled centering balloon located on the catheter for placement adjacent the target site, over a guide wire into the lumen of the blood vessel until said centering balloon is positioned at the target site;

inflating said centering balloon through an inflation lumen of the radiation catheter to position said radiotherapy lumen of the catheter at substantially the radial

center of the vessel lumen at the target site and to allow perfusion of blood past the inflated centering balloon through channels formed thereby;
advancing a source wire having a distal radioactive source of predetermined activity through said radiotherapy lumen of the catheter from the proximal opening thereof until the radioactive source is within a region of the inflated centering balloon at the target site; and

withdrawing the source wire from said radiotherapy lumen of the catheter at the end of a predetermined time interval of said radioactive source being positioned at the target site.

55. (Previously Presented) The method of claim 54, including selecting a super-elastic material for the non-radioactive portion of the source wire.

56. (Previously Presented) The method of claim 55, including selecting a nickel-titanium alloy as the super-elastic material.

57. (Currently Amended) The method of claim 54, including:

coupling the proximal end of the radiation catheter to an afterloader, and wherein ~~performing the steps of advancing and withdrawing the source wire through the radiotherapy lumen of the catheter from and is retracted~~ to a storage location in said afterloader.

58. (Currently Amended) The method of claim 57, including:

threading the guide wire through a guide wire lumen of the radiation catheter eccentrically offset relative to said radiotherapy lumen as part of the step of introducing of the radiation catheter over the guide wire, and

keying the coupling of the proximal end of the radiation catheter to the afterloader to restrain the catheter and guide wire from undergoing rotation in the blood vessel during performance of the method.

59. (Previously Presented) The method of claim 54, wherein said predetermined activity level of the radioactive source and said predetermined time interval in which the radioactive source is positioned at the target site are calculated to enable delivery of a dose of radiation in a range from about 1,000 rads to about 1,500 rads to tissue in the vessel wall in proximity to the vessel lumen at the target site.

60. (Cancelled)

61. (Previously Presented) A method of treating the wall of a blood vessel, comprising:

advancing a guidewire to a treatment site in the blood vessel;
advancing a catheter having a guidewire lumen over the guidewire to the treatment site;
advancing a radioactive source through a working lumen of the catheter, the distal end of the working lumen being located proximal to the distal tip of the catheter, and

using a centering catheter as said catheter to maintain the radioactive source at substantially the radial center of the lumen of the blood vessel after advancement of the source to the treatment site.

62. (Previously Presented) The method of claim 61, including using a centering catheter with at least one passageway for adequate blood flow through the vessel while said radioactive source is maintained at substantially the radial center of the vessel lumen.

63. (Previously Presented) The method of claim 62, including using a centering catheter having an inflatable centering balloon with channels for enabling both the radial centering of and blood flow past the catheter.

64. (New) A method as in claim 17 wherein said balloon, when inflated, centers said radiotherapy lumen without dilating the vessel lumen.

65. (New) A method as in claim 23 wherein the centering device, when deployed, does not dilate the lumen of the duct.

66. (New) A method as in claim 28 wherein a centering device allows the perfusion and centers the radioactive material without dilating the lumen of the vessel.

67. (New) A method of treating a body duct with a centering catheter from within the lumen of the duct, which comprises:

inserting the centering catheter into the lumen of the body duct to position a centering device of said catheter at a site of the duct to be treated; deploying said centering device of the catheter to position a radiotherapy lumen of the catheter at substantially the radial center of the lumen of the duct at said site; advancing material having a predetermined level of radioactivity into said radiotherapy lumen of the catheter to a position at said site; retracting said radioactive material after a predetermined time interval at said site, wherein the centering device, when deployed, does not dilate the lumen of the duct.

68. (New) A method as in claim 33 wherein a centering device allows the perfusion and centers the radioactive material without dilating the lumen of the blood vessel.

69. (New) A method as in claim 38 wherein a centering device allows the perfusion and centers the source material without dilating the duct.

70. (New) A method as in claim 40 wherein a centering device allows the passage of fluid and centers the source material without dilating the duct.

71. (New) A method as in claim 44 wherein a centering device allows the passage of blood and centers the source without dilating the duct.

72. (New) A method as in claim 48 wherein said balloon, when inflated, centers said radioactive distal tip without dilating said target site.

73. (New) A method as in claim 54 wherein the inflated centering balloon centers the radioactive source without dilating the target site.